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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,974	03/02/2006	Toshiyuki Takagi	DAISAN126511	9465

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EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
08/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,974	TAKAGI ET AL.	
	Examiner	Art Unit	
	KEVIN WEDDINGTON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,31,33 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25, 31, 33 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The finality of the Office action dated July 7, 2009 is withdrawn and vacated.

Claims 25, 31, 33 and 36 are presented for examination.

Applicants' amendment and response filed April 15, 2009 have been received and entered.

Accordingly, the rejection made under provisional obviousness-type double patenting over claims 41, 43-47, 57, 59 and 60 of copending Application No. 10/555,076 as set forth in the previous Office action dated December 4, 2008 at pages 2-3 as applied to claims 13, 25, 33, 36 and 37 is hereby withdrawn because the applicants filed a terminal disclaimer.

Accordingly, the rejection made under 35 USC 112, first paragraph (New Matter) as set forth in the previous Office action dated December 4, 2008 at pages 3-4 as applied to claims 13, 25, 31, 33 and 35 is hereby withdrawn because the applicants amended the claims to delete the new matter phrase, "wherein glucose uptake does not include glucose transport".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 31 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman et al., Circulation of PTO-1449, of record, for reason of record as set forth

in the previous Office action dated December 4, 2008 at page 4 as applied to claims 13, 25 and 36.

Applicants' remarks are not persuasive since the same compound (pravastatin) treatment practice to the same patient type as instantly claimed is set forth in the prior art. The instant applicants' measurement of a different molecular target is reasonably a new measurement of the practice of an invention already in the prior art and that applicants have not negated the factual basis for the rejection which is that the same compound is being administered to the same patient in the cited prior art as instantly claimed and the applicants' measurement of molecular targeting does not distinguish the claimed practice over the prior art.

The claims of new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (See In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)).

The rejection made under 35 USC 102(b) is adhered to.

Claims 25, 31 and 36 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25, 31, 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al., Circulation of PTO-1449 in view of Weiner et al. (5,643,868) and further in view of Paolisso et al., European Journal of Clinical Pharmacology, Vol. 40, No. 1, pp. 27-31 (1991), all of record, for reasons of record as set forth in the previous Office action dated December 4, 2008 at pages 5-6 as applied to claims 31-35.

Again, KSR forecloses the remarks that a **specific** teachings, suggestion, or motivation is required to support a finding obviousness. See the recent Board decision

Ex parte Smith, --USPQ2d--, slip op at 20, (Bd., Pat. App. & Interf, June 25, 2007) (citing KSR, 82 USPQ2d at 1396).

The rejection made under 35 USC 103(a) is adhered to.

Claims 25, 31, 33 and 36 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN WEDDINGTON whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm - 9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN WEDDINGTON
Primary Examiner
Art Unit 1614

/KEVIN WEDDINGTON/

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